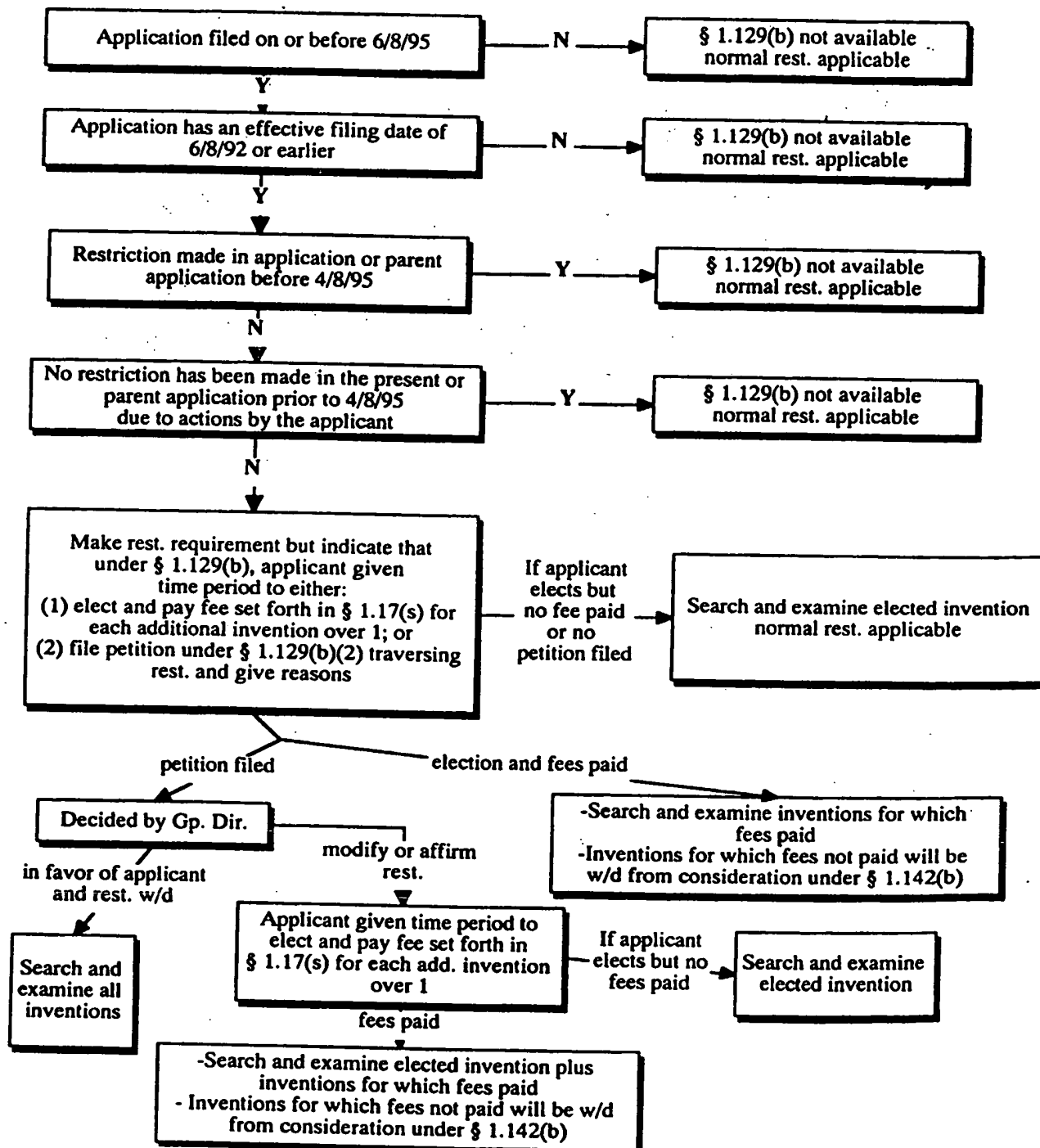
**Transitional Restriction Provision - 37 CFR 1.129(b)****Starting June 8, 1995****No Telephone restriction****Charge time for examination of additional inventions to 112055**



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186

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09/30/91

☐ This application has been examined ☐ Responsive to communication filed on \_\_\_\_\_ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 0 month(s), 30 days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892.        | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948.                  |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.             | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152 |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____   |

**Part II SUMMARY OF ACTION**

1. ☒ Claims 1-34 are pending in the application.  
Of the above, claims \_\_\_\_\_ are withdrawn from consideration.
2. ☐ Claims \_\_\_\_\_ have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☐ Claims \_\_\_\_\_ are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☒ Claims 1-34 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received  
☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-7, 9 and 10, drawn to methods of treating cancer with cyclophosphamide and a vaccine of tumor cells conjugated to a hapten, classified in Class 424, subclass 88.

II. Claims 8, drawn to a method of treating cancer using cyclophosphamide and a vaccine composed of purified tumor antigens, classified in Class 424, subclass 88.

III. Claims 11-17, 19-22, drawn to a method of treating cancer using cyclophosphamide, the vaccine of hapten-conjugated tumor cells and IL-2, classified in Class 424, subclass 85.2.

IV. Claim 18, drawn to a method of treating cancer using cyclophosphamide, a vaccine composed of tumor cell antigens conjugated to a hapten and IL-2, classified in Class 424, subclass 85.2.

V. Claims 23-34, drawn to a vaccine composed of irradiated tumor cells or tumor cell extracts conjugated to a hapten, classified in Class 424, subclass 88.

Inventions (I-IV) and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the vaccine compositions can be used in materially different processes of treating cancer which using the vaccine alone or in combination with other agents besides cyclophosphamide and IL-2.

The methods of treating cancer in Groups I-IV are patentably distinct inventions because they comprise different components and different steps. Invention I is a method of treating cancer which uses cyclophosphamide and the whole tumor cell vaccine; invention II is a method using cyclophosphamide and a vaccine composed of purified tumor antigens; and inventions III is a method comprising the administration of cyclophosphamide, the whole tumor cell vaccine and IL-2; and invention IV is a method comprising the administration of cyclophosphamide, a vaccine composed of purified tumor cell antigens and IL-2. Therefore, inventions I-IV are novel and unobvious over each other and are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be

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examined even though the requirement be traversed.

Lisa T. Bennett

*LJB*



*M. Moskowitz*  
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SUPERVISORY  
PATENT EXAMINER  
ART UNIT 186